LEGISLATIVE COUNSEL BUREAU

A TRADITION OF TRUSTED LEGAL SERVICE TO THE CALIFORNIA LEGISLATURE

LEGISLATIVE COUNSEL BUREAU
925 L STREET
SACRAMENTO, CALIFORNIA 95814
TELEPHONE (916) 341-8000
FACSIMILE (916) 341-8020
INTERNET WWW.LEGISLATIVECOUNSEL.CA.GOV

June 28, 2019

Honorable Jim Wood
Room 6005, State Capitol

ASSEMBLY BILL NO. 290: DIALYSIS PROVIDERS: CHARITABLE DONATIONS - #1916414

Dear Mr. Wood:

Under federal law, the Office of Inspector General in the federal Department of Health and Human Services (hereafter OIG) may issue advisory opinions to parties seeking advice about whether a proposed or current business arrangement complies with the Health Insurance Portability and Accountability Act of 1996.[1] In 1997, the OIG issued an advisory opinion generally approving an arrangement between the American Kidney Fund (hereafter AKF) and various dialysis providers.[2]

In this context, you have asked whether AKF would remain in compliance with that approved arrangement if Assembly Bill No. 290 (2019-2020 Reg. Sess.) (hereafter AB 290) is enacted and the AKF complies with the requirements of that bill.

1. Background

1.1 AB 290

AB 290 would limit the reimbursement rate for dialysis providers that are "financially interested." The bill would define "financially interested" to include "An entity that receives the majority of its funding from one or more financially interested providers of health care services, parent companies of providers of health care services, subsidiaries of

[1] Social Security Act, § 1128D(b); see also United States Department of Health and Human Services, OIG internet website, available at <https://oig.hhs.gov/faqs/advisory-opinions-faq.asp> (last accessed June 27, 2019).

[2] OIG, Advisory Opinion No. 97-1, available at <https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp#1997> (last accessed June 27, 2019) (hereafter Opinion 97-1).

health care service providers, or related entities."[3] Under AB 290, the reimbursement rate for such a financially interested dialysis clinic would be the Medicare reimbursement rate.[4]

Additionally, AB 290 would require a financially interested entity to disclose to the health care service plan or insurer the name of each patient for whom it pays a premium. Specifically, the bill would prohibit such an entity from making a third-party premium payment unless it discloses to the health care service plan or health insurer, as applicable, the name of the enrollee or insured for each health care service plan contract or policy on whose behalf a third-party premium payment will be made.[5]

1.2 Section 1128A(a)(5) of the Social Security Act

Section 1128A(a)(5) of the Social Security Act (hereafter section 1128A(a)(5)), enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), prohibits certain offers or transfers of remuneration to a Medicare or Medicaid beneficiary. Specifically, section 1128A(a)(5) imposes civil penalties against any person who

> "offers or transfers remuneration to any individual eligible for benefits under [Medicare or Medicaid] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid]."

Section 1128A(i)(6) of the Social Security Act defines "remuneration" for these purposes as including "the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value."

As will be discussed in greater detail below, this prohibition has been interpreted by the OIG to prohibit a provider from paying the premiums of patients directly, but does not, under certain circumstances, prohibit a third-party entity (such as a nonprofit organization) from making premium payments on behalf of patients.

---

[3] Proposed Health & Saf. Code, § 1367.016, subd. (f)(2)(B) & Ins. Code, § 10176.11, subd. (f)(1)(B). The bill also defines "financially interested" to include "A provider of health care services that receives a direct or indirect financial benefit from a third-party premium payment" and "A chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019." (Proposed Health & Saf. Code, § 1367.016, subd. (f)(1)(A) & (C) & Ins. Code, § 10176.11, subd. (f)(1)(A) &(C).)

[4] See proposed Health & Saf. Code, § 1367.016, subd. (d) & Ins. Code, § 10176.11, subd. (d).

[5] Proposed Health & Saf. Code, § 1367.016, subd. (c)(2) & Ins. Code, § 10176.11, subd. (c)(2).

The OIG, which was established in the Department of Health and Human Services to identify and eliminate fraud, abuse, and waste in the department's programs, is responsible for enforcing section 1128A(a)(5).[6] Additionally, Congress has authorized the OIG to create regulatory exceptions to section 1128A(a)(5) and to issue advisory opinions to protect acceptable arrangements.[7] When the OIG issues an advisory opinion, it protects the arrangement described in that particular opinion and is binding only with respect to the parties that requested the opinion. It does not establish any legal precedent upon which other parties may rely.[8] Additionally, advisory opinions rely solely on the facts presented to the OIG by the parties to the letter. "If material facts have not been disclosed, [the] opinion is without force and effect."[9] Moreover, an advisory opinion "is limited in scope to the specific arrangement described in [the opinion] and has no applicability to other arrangements, even those which appear similar in nature or scope."[10]

1.2.1 Patient assistance programs

Patient assistance programs provide financial assistance to patients, which may take the form of assistance with the payment of health insurance premiums. Under federal law, financial assistance given directly by a provider to a patient would likely violate section 1128A(a)(5) because this would constitute "remuneration" to an individual patient that would influence the patient's choice of provider.[11] To avoid violating the law, some health care providers have entered into agreements to provide funding for financial assistance to be administered by independent charitable organizations.[12] The OIG determined, beginning in 1997, that these arrangements were lawful in the context of facts provided by the requesters indicating that certain safeguards relating to the independence and autonomy of the charity were in place.[13] The first advisory opinion analyzing such an arrangement was Opinion 97-1, in which the OIG analyzed a particular patient assistance program involving AKF. AKF, which is a charitable and educational organization organized under section 501(c)(3) of the federal Internal Revenue Code, entered into an arrangement with certain dialysis providers whereby the providers contribute funds to AKF, which in turn

---

[6] See OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, 67 Fed.Reg. 55855 (Aug. 30, 2002) (hereafter 2002 Special Advisory Bulletin).

[7] See § 1128A(i)(6)(B) & 1128D(b)(2)(A) of the Social Security Act.

[8] See § 1128D(b)(4)(A) of the Social Security Act; Opinion 97-1, p. 1.

[9] Opinion 97-1, p. 1.

[10] Opinion 97-1, p. 6.

[11] § 1128A(a)(5); see Medicare and State Health Care Programs: Fraud and Abuse; Civil Money Penalty Exception To Protect Payment of Medicare Supplemental Insurance and Medigap Premiums for ESRD Beneficiaries, 67 Fed.Reg. 72896-01 (Dec. 9, 2002).

[12] See Gosfield, *Beneficiary Inducements: What's New and What's Still True*, 2018 Health L. Handbook 10.

[13] See Opinion 97-1.

independently screens patients for financial need and pays Medicare Part B and Medigap premiums on behalf of qualifying patients. We turn now to a discussion of this arrangement as analyzed by the OIG in Opinion 97-1.

1.3 Opinion No. 97-1

In Opinion 97-1, the OIG analyzed the arrangement between AKF and the donor providers for compliance with section 1128A(a)(5). The OIG noted that the arrangement contains the following elements: (1) AKF pays the premiums for financially needy end-stage renal disease patients, and this financial assistance is available to all eligible patients on an equal basis.[14] (2) Providers that make financial donations to AKF agree not to advertise the availability of possible financial assistance to the public and not to disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants.[15] (3) AKF staff involved in awarding patient grants do not take into consideration the amount of any provider's donation when assessing patient applications or making grant determinations.[16] (4) The donating companies certify that they will not track the amount that AKF pays on behalf of patients dialyzing at their facilities in order to calculate future contributions. Furthermore, the companies will not disclose to each other, or other dialysis providers, the amount or method of calculating their respective contributions to AKF, and AKF will not disclose one company's contribution to another company or to dialysis providers.[17] (5) There are no restrictions or conditions put on donations, and AKF's discretion as to the uses of contributions is absolute, independent, and autonomous.[18]

The OIG concluded in Opinion 97-1 that the above-described arrangement is allowable under section 1128A(a)(5) because (1) the donations to AKF do not constitute "remuneration" to an eligible patient; and (2) AKF's purchase of premiums is unlikely to influence patients to receive services from particular providers.[19] We address each element of the OIG's analysis in turn.

1.3.1 Donations to AKF are not remuneration

The OIG found that the contributions in question are not made to or on behalf of an individual. In this regard, the OIG emphasized that under the arrangement, AKF has absolute discretion regarding the use of provider contributions made to AKF. Moreover, eligibility for assistance is available to any financially needy patient regardless of provider; it is not limited to patients of the providers. Last, as an "additional safeguard," the providers

---

[14] Opinion 97-1, p. 2.
[15] Opinion 97-1, p. 3.
[16] Opinion 97-1, p. 3.
[17] Opinion 97-1, p. 3.
[18] Opinion 97-1, p. 4.
[19] Opinion 97-1, pp. 4-5.

agreed not to track the amounts that AKF pays on behalf of patients dialyzing at their facilities in order to calculate amounts of future contributions.[20] The OIG stated as follows:

> "In sum, the interposition of AKF, a bona fide, independent, charitable organization, and its administration of [the program] provides sufficient insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of [program] assistance their patients receive bears any relationship to the amount of their donations."[21]

Thus, the OIG concluded that the payments made on behalf of patients do not constitute "remuneration" under section 1128A(a)(5).

1.3.2 AKF's purchase of premiums is unlikely to influence patient's choice of provider

With respect to whether the payments are likely to influence patients in their choice of providers, the OIG opinion emphasized that in most circumstances a patient will have already selected a provider before applying to AKF for premium assistance. In addition, under the arrangement, the patient assistance programs will not be advertised to the public, reducing the chance that a beneficiary will choose a provider based on its participation in such a program.[22] And "most importantly," the OIG emphasized that a beneficiary may "select any provider . . . . Simply put, AKF's payment of premiums will expand, rather than limit, beneficiaries' freedom of choice."[23] Thus, the OIG determined that the payments made on behalf of a patient were not likely to influence the patient's choice of provider. Because the OIG found that those payments would neither constitute remuneration nor be likely to influence a patient's choice of provider, it concluded that the arrangement would not violate section 1128A(a)(5).

Despite the fact that advisory opinions issued by the OIG are binding only as to the parties involved, it is possible to draw inferences as to what types of arrangements the OIG deems permissible under HIPAA based on the analysis contained in those advisory opinions. We now apply the analysis contained in Opinion 97-1 to the requirements that would be imposed by AB 290.

2. Analysis

You have informed us that AKF receives the majority of its funding from one or more financially interested providers of health care services, parent companies of providers of health care services, subsidiaries of health care service providers, or related entities and would

---

[20] Opinion 97-1, p. 5.
[21] Opinion 97-1, p. 5.
[22] Opinion 97-1, p. 5.
[23] Opinion 97-1, p. 5.

thus meet this definition of a "financially interested" entity for purposes of the disclosure provisions required by AB 290. Therefore, AKF would be subject to the disclosure requirements specified in that bill.[24] These disclosure requirements would require AKF to provide personally identifiable patient information to the health care service plan or insurer that receives premium payments on behalf of a beneficiary.[25]

Opinion 97-1 states, "The OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion as long as . . . the arrangement in practice comports with the information provided."[26] Because these disclosure requirements were not part of the arrangement considered by the OIG when it issued Opinion 97-1, that opinion would not ensure that the version of the patient assistance program operated by AKF in compliance with AB 290 would be immune from OIG sanctions. In this regard, Opinion 97-1 specifically states that it "is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope."[27]

However, although the changes in the premium assistance program required by AB 290 would remove the legal protection afforded by Opinion 97-1, that fact does not mean that the program would violate section 1128A(a)(5). It is possible that the changes to the program necessitated by the enactment of AB 290 would not change the reasoning underlying the opinion and that the OIG would continue to consider the arrangement, as modified, to be compliant with section 1128A(a)(5). Thus, we must consider whether, based on the reasoning in Opinion 97-1, the patient assistance program described in that opinion would violate section 1128A(a)(5), as construed by the OIG, if the arrangement was altered to comply with the requirements of AB 290.

As discussed previously, one element of the arrangement addressed in Opinion 97-1 that was deemed relevant by the OIG was the fact that the companies that donate to AKF will not track the amounts that AKF pays on behalf of patients receiving treatment at their facilities in order to calculate amounts of future contributions. Additionally, the OIG stated that the donors "will not advertise the availability of possible financial assistance to the public and will not disclose directly or indirectly to individual patients they refer that such members have contributed to AKF to fund the grants."[28] In its conclusion, the OIG noted:

> "[T]he interposition of AKF, a bona fide, independent, charitable organization, and its administration of [the program] provides sufficient

---

[24] See proposed Health & Saf. Code, § 1367.016, subd. (c)(2); Ins. Code, § 10176.11, subd. (c)(2).

[25] Proposed Health & Saf. Code, § 1367.016, subd. (c)(2); Ins. Code, § 10176.11, subd. (c)(2).

[26] Opinion 97-1, p. 6.

[27] Opinion 97-1, p. 6.

[28] Opinion 97-1, p. 3.

> insulation so that the premium payments should not be attributed to the Companies. The Companies who contribute to AKF will not be assured that the amount of . . . assistance their patients receive bears any relationship to the amount of their donations. Indeed, the Companies are not guaranteed that beneficiaries they refer to [the program] will receive any assistance at all. In these circumstances, we do not believe that the donations by the Companies to AKF can reasonably be construed as payments to eligible beneficiaries of a Federal health care program."[29]

Thus, the donors' lack of knowledge regarding the identities of patients receiving financial assistance and the patients' lack of knowledge regarding the sources of donations were important factors in the OIG's approval of the arrangement.

We think that AB 290 raises two relevant concerns with respect to its disclosure requirements: the possibility that a provider may discover the identity of a patient receiving assistance from AKF and the possibility that a patient receiving assistance may discover that the patient's provider donated to AKF. We address each of these concerns separately below.

2.1 Disclosing the identity of patients to donors

The patient data specified in AB 290 is required to be reported to the health plan or insurer. There is no indication in the bill that the information will be reported to the dialysis provider that donated funds to AKF. However, if under certain factual scenarios, the provider becomes aware of the identity of patients who are receiving assistance from AKF (by, for example, receiving a lower reimbursement rate from the insurer once the reimbursement cap imposed by AB 290 took effect), it could be possible for the provider to infer that the reason for the lower reimbursement was the fact that the patient had received assistance from AKF. In this manner, the provider could indirectly be provided with information that leads to the conclusion that the patient had received premium assistance.

However, we note that the bill does not require the identity of patients to be provided directly to donors and that the manner in which a provider may discover the identity of patients receiving assistance in the hypothetical situation described above is indirect. It is possible that the OIG would deem this connection to be too attenuated to create a violation of section 1128A(a)(5). Moreover, even if the donors are indirectly made aware that the reimbursement rates for certain patients changed after the enactment of AB 290, so long as the donor agreed not to take steps to track this information, the arrangement could still be in compliance with the arrangement approved in Opinion 97-1.

2.2 Disclosing the identity of donors to patients

The prohibition specified in section 1128A(a)(5) indicates that it applies only to remuneration that influences a patient's choice of provider. In Opinion 97-1, the OIG discusses

---

[29] Opinion 97-1, p. 5.

the fact that in most circumstances a patient will have already selected a provider before applying to AKF for premium assistance and that the patient assistance programs will not be advertised to the public, reducing the chance that a beneficiary will choose a provider based on its donations to a patient assistance program.[30] This suggests that if a patient has already selected a provider, the patient would not be influenced if the patient subsequently discovered that a provider had donated funds to AKF. However, in its 2002 Special Advisory Bulletin, the OIG suggests that even patients who have already selected a provider could be unlawfully "induced" to continue receiving services from the provider, stating that "the OIG considers the provision of free goods or services to existing customers who have an ongoing relationship with a provider likely to influence those customers' future purchases."[31]

With respect to whether compliance with AB 290 would result in the unlawful inducement of patients by providers, the bill does not expressly require or authorize a patient to be informed of whether a particular provider has donated to AKF. However, if AB 290 is enacted, it may be possible under certain factual scenarios for a patient to infer that the patient's provider had donated. For example, a patient may receive a billing statement showing that the patient's reimbursement rate had been lowered to the Medicare reimbursement rate. That patient could infer that the reason for the lower rate was the fact that the provider was a "financially interested" entity under AB 290 as a result of donations to AKF.[32] This inference could thus influence the patient to remain with the provider.

Nevertheless, the connection between the disclosure requirements mandated by AB 290 and the patient's discovery that a provider donated to AKF is arguably attenuated, and in any case, it is possible that the OIG would not find it to be a significant enough factor in affecting the patient's choice of provider to make the arrangement inconsistent with the one approved in Opinion 97-1.

We conclude that based on the facts available to us, AKF would remain in compliance with the arrangement approved in Opinion 97-1 if AB 290 is enacted and AKF complies with the changes required by that bill. However, this would be a factual determination made by the OIG and could involve a consideration of facts not available to us.[33]

---

[30] Opinion 97-1, p. 5.

[31] 2002 Special Advisory Bulletin, p. 3.

[32] However, we note that AB 290 defines "financially interested" as including "[a] chronic dialysis clinic that is operated, owned, or controlled by a parent entity or related entity that meets the definition of a large dialysis clinic organization (LDO) under the federal Centers for Medicare and Medicaid Services Comprehensive ESRD Care Model as of January 1, 2019." (Proposed Health & Saf. Code, § 1367.016, subd. (f)(1)(C) & Ins. Code, § 10176.11, subd. (f)(1)(C).) Because such a clinic need not have donated to a patient assistance program to be considered "financially interested," the reimbursement rate would not necessarily indicate that the provider had donated to such a program.

[33] Although the analysis in Opinion 97-1 is limited to a discussion of section 1128A(a)(5), subsequent OIG advisory opinions have also discussed the federal

(continued . . .)

3. Conclusion

It is our opinion that based on the facts available to us, the American Kidney Fund would remain in compliance with the arrangement approved in Advisory Opinion 97-1 issued by the Office of the Inspector General of the federal Department of Health and Human Services if Assembly Bill No. 290 (2019-2020 Reg. Sess.) is enacted and the American Kidney Fund complies with the changes enacted by that bill. However, this would be a factual determination made by the Office of Inspector General and could involve a consideration of facts not available to us.

Very truly yours,

Diane F. Boyer-Vine
Legislative Counsel

By Amy Schweitzer
Amy E. Schweitzer
Deputy Legislative Counsel

AES:blt

(. . . continued)
prohibition on kickbacks in analyzing patient assistance programs. In this regard, the anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. (OIG, Advisory Opinion No. 06-04, available at <https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp#2006> (last accessed June 27, 2019).) However, "[a] determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all the relevant facts and circumstances, including the intent of the parties." (OIG Special Advisory Bulletin, Patient Assistance Programs for Medicare Part D Enrollees 70 Fed.Reg. 70623 (Nov. 22, 2005).)